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April 21, 2021

VIA ECF
The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, DE 19801-3570

Re: ***H. Lundbeck A/S, et al. v. Lupin Limited, et al.*, No. 18-cv-88**

Dear Chief Judge Stark:

I am writing on behalf of Defendants in connection with the motion to strike that Plaintiffs raised for the first time in their Post-Trial Reply Brief ("Pls. Reply") this past Tuesday, April 13. D.I. 1054 at 41-44. Defendants respectfully request that the court strike or, in the alternative, deny Plaintiffs' late motion.

In their Reply, Plaintiffs move to strike DTX1138 in violation of Local Rule 7.1.3(c)(2), which requires that "[t]he party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief." Pls. Reply 41-44. Plaintiffs objected to DTX1138 during trial and Your Honor overruled those objections and admitted DTX1138 into evidence. Your Honor also made clear that if Plaintiffs wished to challenge that ruling, then the burden was on Plaintiffs to move to strike that exhibit in the post-trial briefing:

> THE COURT: All right. I will overrule the objection and I will admit [DTX1138] and let it into evidence. If the [P]laintiffs want to move to strike in the course of the post-trial briefing, they can. But I'm persuaded that there is a basis to admit it and give it whatever weight it deserves.

Tr. 152:12-16. Accordingly, if Plaintiffs intended to re-raise their objections, they should have moved to strike this exhibit in their opening post-trial brief. By waiting until their reply brief to raise this motion, Plaintiffs have deprived Defendants of a full opportunity to respond.[1]

To the extent the Court considers Plaintiffs' untimely motion to strike, it should be denied because DTX1138 falls into multiple exceptions to the hearsay rule, as Defendants noted at trial. Tr. 150:22-151:20. First, DTX1138 reports survey results that Plaintiffs collected when they were drafting the Trintellix® labeling. DTX1138.1-.3. Plaintiffs' marketing department provided this survey report to the inventor of the '096 patent, Dr. Marianne Dragheim, in the ordinary course of business and thus it qualifies as admissible evidence under at least FRE 803(6). Tr. 150:22-151:2, 143:16-144:10; DTX1137.

[1] Plaintiffs argue that they did not move to strike DTX1138 in their opening brief because they did not know if Defendants would rely on it in post-trial briefing. Pls. Reply 41 n.18. This excuse is without merit because: (a) Defendants had already relied on DTX1138 at trial; and (b) Your Honor admitted DTX1138 and told Plaintiffs they needed to move to strike if they disagreed. Thus, this dispute was fully ripe at the time of Plaintiffs' opening brief. Plaintiffs also disregarded the detailed procedure for Motions to Strike that are set forth in the Scheduling Order. D.I. 31, ¶ 10.

Consequently, Plaintiffs' allegation that Defendants "tried to shoehorn DTX-1138 into evidence through a fact witness with no knowledge of it" is not true. Pls. Reply 42. Plaintiffs' arguments regarding the inadmissibility of the physician statements contained in the report should likewise be rejected. Pls. Reply 42-43. The physician statements are admissible under, at least, FRE 803(1) as present sense impressions reported to the researchers immediately after reviewing "stimulus materials" related to the Plaintiffs' label during a videoconference. DTX1138.4-.6. At minimum, the physicians made statements of their "then-existing states of mind" under FRE 803(3). *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 223, 229 (2d Cir. 1999) (Sotomayor, J.) (holding physician surveys admissible under 803(3)).

Second, surveys like DTX1138 have often been admitted under the residual hearsay exception of FRE 807. *E.g.*, *Deere & Co. v. FIMCO Inc.*, 260 F. Supp. 3d 830, 840-43 (W.D. Ky. 2017); *Bodeans Cone Co. L.L.C. v. Norse Dairy Sys. L.L.C.*, 678 F. Supp. 2d 883, 903-05 (N.D. Iowa 2009); *Schering Corp. v. Pfizer Inc.*, No. 98-cv-7000, 2000 U.S. Dist. Lexis 7071, *10-16 (S.D.N.Y. May 24, 2000). Like these cases, the present survey meets the trustworthiness requirement of FRE 807(a)(1) because there is no reason to believe that: physicians would have made false statements in response to the survey; or the company that Plaintiffs themselves commissioned to prepare the survey report did so inaccurately. Indeed, Plaintiffs make no such claims. Instead, Plaintiffs' attempt to impugn the survey as not "properly conducted" by pointing to several inapposite cases in which a party challenged the admissibility of an ***opponent's*** survey. Pls. Reply 41-43 (citing *Pittsburgh Press Club v. United States*, 579 F.2d 751 (3d Cir. 1978); *AAMCO Transmissions, Inc. v. Baker*, 591 F. Supp. 2d 788 (E.D. Pa. 2008); *United States v. Wilmington Tr. Corp.*, No. 15-cr-23, 2017 WL 4480787 (D. Del. Oct. 6, 2017)). By contrast, Plaintiffs are challenging the trustworthiness of ***their own*** survey report, which they commissioned when drafting the Trintellix® label. DTX1138.1-.6. There are simply no indicia of untrustworthiness under such facts. *See Bodeans*, 678 F. Supp. at 904 ("It is difficult for the court to take seriously 'trustworthiness' challenges to a survey made by the very party that commissioned and used the survey in the first instance, albeit not for purposes of the present litigation.").

Plaintiffs' attack on whether DTX1138 meets the probativeness requirement of FRE 807(a)(2) also falls flat. Pls. Reply 43-44. Plaintiffs' inducement allegations center on how prescribers will interpret the ASEX data in Section 6.1 of Defendants' prescribing information. D.I. 1013 at 74-77. As shown in the side-by-side comparison below, the survey reported in DTX1138 evaluated that same data—the minor differences are non-substantive. Plaintiffs have identified no reason a prescriber would read this data differently today than in 2012.

Draft Labeling Provided in Survey

Table 4: Incidence of Sexual Dysfunction Based on Arizona Sexual Experience Scale (ASEX)*

	Product M					Placebo
	5 mg/day	10 mg/day	15 mg/day	20 mg/day	Total 5-20 mg/day	
Females	14/65 (22%)	22/94 (23%)	19/57 (33%)	23/67 (34%)	78/283 (28%)	27/135 (20%)
Males	11/67 (16%)	17/86 (20%)	13/67 (19%)	17/59 (29%)	58/279 (21%)	22/162 (14%)

* Incidence based on number of subjects with sexual dysfunction during the study [n] / number of subjects without sexual dysfunction at baseline [N]. Sexual dysfunction was defined as a subject scoring any of the following on the ASEX scale at two consecutive visits during the study: 1) total score ≥19; 2) Any single item ≥5; 3) three or more items each with a score ≥4.

DTX1138.20

Exemplary Defendant Labeling

Table 3
ASEX Incidence of Treatment Emergent Sexual Dysfunction*

	Vortioxetine 5 mg/day N=65:67†	Vortioxetine 10 mg/day N=94:86†	Vortioxetine 15 mg/day N=57:67†	Vortioxetine 20 mg/day N=67:59†	Placebo N=135:162†
Females	22%	23%	33%	34%	20%
Males	16%	20%	19%	29%	14%

*Incidence based on number of subjects with sexual dysfunction during the study/number of subjects without sexual dysfunction at baseline. Sexual dysfunction was defined as a subject scoring any of the following on the ASEX scale at two consecutive visits during the study: 1) total score ≥19; 2) any single item ≥5; 3) three or more items each with a score ≥4

† Sample size for each dose group is the number of patients (females:males) without sexual dysfunction at baseline

DTX1933.12

Finally, the equities counsel in favor of applying the residual exception to DTX1138. Defendants

provided sufficient notice under FRE 807(b) of their intent to rely on DTX1138 by putting it on their exhibit list in the pretrial order in January 2021. D.I. 985, Ex. 12 at 72. Plaintiffs could have challenged it before trial or presented evidence during trial attacking the reliability of the report—long before reply post-trial briefing—but they chose not to do so. By contrast, Defendants had no reason during the fact discovery period to seek discovery to cement DTX1138's admissibility. During fact discovery, Plaintiffs were alleging only contributory infringement of the '096 patent and did not rely on Defendants' prescribing information for that purpose. D.I. 1013 at 99 (arguing prescribing information not relevant to contributory infringement). Only with the addition of induced infringement to the case in June 2020 (D.I. 801)—nearly six months after the close of fact discovery (D.I. 634)—did DTX1138's survey about physicians' views of the prescribing information become highly relevant to the issues in this litigation. Plaintiffs assured the court when they moved for leave to add their inducement allegations that doing so would not prejudice Defendants. D.I. 742 at 3. However, excluding DTX 1138 would do exactly that.

* * *

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to strike DTX1138. To the extent the Court deems it necessary, Defendants request leave of Court to file this request to strike or deny Plaintiffs' motion.

Respectfully submitted,

/s/ Dominick T. Gattuso

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DTG/ram

cc: All Counsel of Record (via e-mail)